

Remarks

Claims 14-29, 35, 36, and 39-47 are pending upon entry of the foregoing amendments.

Amendments to the Specification

The specification has been amended to correct an obvious typographical error.

Amendments to the Claims

Claims 1-13, 30-34, 37, and 38 have been canceled without prejudice, as being directed to a non-elected invention.

Claim 14 has been amended to specify that the microtubes are constructed of a metal or an alloy. Support for this amendment is found in the specification at least at page 14, line 25 to page 15, line 30; and page 17, line 18 to page 18, line 15. Claim 14 also has been amended to more clearly recite that the rupturable covering closes an opening at a first end of each reservoir and that rupture of the rupturable covering results in displacement of the release formulation through the opening.

Claims 18, 26, and 29 have been amended to correct the antecedent bases of the claims.

Claim 19, which the Examiner deemed as being directed to allowable subject matter, has been amended into independent form.

New claims 39-47 have been added. Support for these claims is found in the original claims and at least at page 7, line 25 to page 8, line 30; page 14, lines 29-30; page 15, line 22 to page 16, line 9; page 17, line 18 to page 18, line 15; page 20, line 8 to page 21, line 121 and FIGS. 6-12. No new matter has been added.

Restriction Requirement and Election

The Office Action divided claims 1-38 into three groups: Group I, claims 1-10, 30, 31, 37, and 38, drawn to devices and methods for the controlled release of chemical molecules from

a plurality of reservoirs; Group II, claims 11-13 and 32-34, drawn to devices and methods for the controlled release of a fluid drug formulation; and Group III, claims 14-29, 35, and 36, drawn to devices and methods for the controlled release of chemical molecules from an array of microtubes. Applicants confirm the provisional election, with traverse, to prosecute Group III, claims 14-29, 35, and 36 in the present application. New claims 39-47 also should be grouped and considered together with claims 14-29, 35, and 36. Applicants traverse the restriction requirement, as it is submitted that Group I and Group III should be considered together given the significant overlap of features between the two groups of claims. Search and examination of Groups I and III together therefore would not require an undue burden.

Rejections under 35 U.S.C. § 112

Claim 14 was rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Claim 14 also was rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The rejections are respectfully traversed.

The rejections appear based on an incomplete understanding of what Applicants have taught in the original application and what is claimed. Applicants' specification and drawings are sufficiently descriptive and enabling such that one of skill in the art would be able to practice the claimed devices and methods without undue experimentation and would be able to readily comprehend the metes and bounds of the claims.

The examiner appears to have mistakenly focused only on FIGS. 6A-6B. It is respectfully noted that the claimed microtube devices are also illustrated by FIGS. 7-12, as described at pages 14-45. While FIG. 6 shows what an *array* of *many* microtubes might look like, FIGS. 7 and 10-12 show cross-sectional views of various possible configurations of

individual microtubes, which could be incorporated into the array of FIG. 6. In addition, FIG. 8C shows how the rupturable coverings in an array might appear with defects corresponding to each microtube. These drawings and their descriptions collectively enable one skilled in the art to understand how a single microtube might be structured and be integrated into a multi-microtube array device.

The examiner also queries whether there is one rupturable covering for all reservoirs or one covering for each reservoir. One skilled in the art reading the present application clearly understands that the claimed devices may have multiple, discrete rupturable coverings, or the rupturable coverings for two or more microtubes may be part of the same monolithic structure. Both cases were envisioned by the Applicants, are taught in the original application, and are intended to be encompassed by Applicants' claims. For example, FIGS. 7 and 10-12 illustrate the former, and FIG. 8C illustrates the latter. In describing FIG. 7, "[t]he rupturable covering 232 may further include a support layer 234 (e.g., a substrate layer that can be etched to create a membrane by exposing the bottom layer) bonded thereto in areas not intended for rupture, i.e. in areas between and joining adjacent microtubes." Page 16, lines 14-17. FIG. 8C "shows one embodiment of a metal foil which comprises an array of defects made therein, each of which could correspond to the rupturable covering of a single microtube." Page 17, lines 26-29. Thus, it is clear and definite that two or more reservoirs may be covered by a single structure or separate structures, and claim 14 is written accordingly.

Rejections under 35 U.S.C. § 103

Claims 14-17, 23, 35, and 36 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,122,128 to Cardinal et al. (hereinafter "Cardinal"). Claim 18 was rejected

under 35 U.S.C. § 103(a) as obvious over Cardinal in view of U.S. Patent No. 4,595,583 to Eckenhoff et al. (hereinafter "Eckenhoff"). Claim 20 was rejected as obvious over Cardinal in view of Eckenhoff and in further view of U.S. Patent No. 6,183,466 to Wong et al. (hereinafter "Wong"). Claim 21 was rejected as obvious over Cardinal in view of U.S. Patent No. 4,950,258 to Kawai et al. (hereinafter "Kawai"). Claim 22 was rejected as obvious over Cardinal in view of Wong. Claim 24 was rejected as obvious over Cardinal in view of U.S. Patent No. 3,762,540 to Baumann et al. (hereinafter "Baumann"). Claims 25-29 were rejected as obvious over Cardinal in view of U.S. Patent No. 5,401,110 to Neeley et al. (hereinafter "Neeley"). The rejections are respectfully traversed.

Applicants Claimed Devices

Applicants have developed microtube array devices for the controlled release of chemical molecules, such as drug formulations. The microtubes are straight-walled structures, constructed of a metal or an alloy, which advantageously can be made with fewer (or no) MEMs processing steps as compared to other micro-reservoir devices. See page 15, lines 3-8.

Cardinal

Cardinal discloses a ruminal bolus comprising a semipermeable membrane defining a compartment. A first compartment portion contains a swellable osmotic material and a second compartment portion contains a medicament to be dispersed. Following ingestion by the ruminant animal, the semipermeable membrane allows water to pass to the swellable osmotic material. The swellable osmotic material then forces an interface between it and the medicament to displace the medicament through an orifice for release into the animal.

The ruminal bolus of Cardinal is plainly not a microtube. Moreover, Cardinal teaches that the bolus is constructed of a membrane permeable to water; it certainly fails to disclose or suggest a microtube *constructed of a metal or an alloy* as required by Applicants' claim 14. Furthermore, Cardinal does not disclose or remotely suggest a device having a *rupturable* covering over a first end of a reservoir. Rather, Cardinal teaches that the semipermeable membrane remains intact while the medicament is released through an orifice. One skilled in the art clearly would have had no motivation to modify the teachings of Cardinal to derive the presently claimed devices and methods, absent improper hindsight reconstruction. Accordingly, not prima facie case of obviousness has been established.

Cardinal In Combination With Other Cited References

Eckenhoff discloses a therapeutic delivery system comprising a gelatin body having a passageway through which a beneficial agent is delivered. Nothing in Eckenhoff, alone or in combination with Cardinal, remotely teaches using an array of microtubes constructed of a metal or an alloy or the use of a rupturable covering over a reservoir to seal and then release chemical molecules.

Wong discloses a capsule for delivering a therapeutic agent to a patient. Nothing in Wong, alone or in combination with Cardinal and/or Eckenhoff, remotely teaches using an array of microtubes constructed of a metal or an alloy or the use of a rupturable covering over a reservoir to seal and then release chemical molecules.

Kawai discloses molded articles comprising polymers that are biodegradable and exhibit shape memory properties. Nothing in Kawai, alone or in combination with Cardinal, remotely

teaches using an array of microtubes constructed of a metal or an alloy or the use of a rupturable covering over a reservoir to seal and then release chemical molecules.

Baumann discloses receptacles having a plurality of chambers for storing substances to make a dental preparation ready for use. The disclosure of Baumann does not supplement the deficiencies of Cardinal. because Baumann does not disclose or suggest, for example, a device having an array of microtubes constructed of a metal or an alloy.

Neely discloses a specimen tube tray having a label maker for specimen gathering. Nothing in Neely supplements the deficiencies of the teachings of Cardinal. For instance, nothing in Neely remotely teaches an array of microtubes constructed of a metal or an alloy or the use of a rupturable covering over a reservoir to seal and then release chemical molecules.

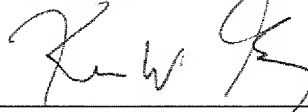
Conclusions

For the foregoing reasons, it is submitted that the claims as amended are novel and non-obvious over the cited prior art. Prompt allowance of each of pending claims 14-29, 35, 36, and 39-47 is therefore respectfully solicited.

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AMENDMENT AND
RESPONSE TO OFFICE ACTION

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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